

**K051133**  
**510(k) SUMMARY**  
**FOR THE**  
**SIREMOBIL C 06**

Submitted by:

Siemens Medical Solutions USA, Inc.  
 51 Valley Stream Parkway  
 Malvern, PA 19355

April 18, 2005

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

**1. Contact Person:**

Michael J. Andrews  
 51 Valley Stream Parkway, E-50  
 Malvern, PA 19355  
 Phone: (610) 448-4599  
 Fax: (610) 448-1787

**2. Device Name and Classification:**

Trade Name: ARCADIS Avantic  
 Classification Name: Mobile X-Ray System  
 Classification Panel: Radiology  
 CFR Section: 21 CFR §892.1720  
 Device Classification: Class II  
 Product Code: 90IZL

**3. Substantial Equivalence:**

The ARCADIS Avantic is substantially equivalent to the following devices:

<i>Predicate Device Name</i>	<i>510(k) Number</i>	<i>Clearance Date</i>	<i>Comparable Properties</i>
Siemens Siremobil C06 Trade name: ARCADIS Varic	K040066	02/12/2004	<ul style="list-style-type: none"> <li>• Hardware</li> <li>• Control Software</li> <li>• Imaging system</li> </ul>
Siemens AXIOM Artis U	K040675	06/10/2004	<ul style="list-style-type: none"> <li>• X-ray features</li> <li>• Intended use</li> </ul>

**4. Device Description:**

The ARCADIS Avantic is an x-ray system which consists of a mobile C-arm configured with a high frequency generator, X-ray tube assembly, image intensifier, TV camera, laser target devices, electronics cabinet, a monitor trolley and digital image storage system which consists of the digital memory device, image monitor(s), and user interface. The system is equipped with a footswitch and a hand switch for radiation release.

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**5. Intended Use of the Device:**

The ARCADIS Avantic is a mobile x-ray system which can operate in six different modes: Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy, Digital Cine Mode DCM, Subtraction, and Roadmapping, which are necessary in performing a wide variety of clinical procedures. Clinical applications may include, but are not limited to card/vascular, gastroenterology, electrophysiology, urologic, orthopedic, neurologic, pediatrics, endoscopy, pain therapy and emergency room procedures

**6. Summary of Technological Characteristics of the Devices Compared to the Predicate:**

The ARCADIS Avantic is a modification to the ARCADIS Varic. Mechanically the changes are minor in design and style. The X-ray generator and X-ray tube are designed to provide the increased power.

The imaging chain reflects the current standard of 1024<sup>2</sup> image processing and display with flat screen monitors. An uninterruptable power supply provides additional safety to image and demographic data in the event of a power outage.



JUN 1 - 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Michael J. Andrews, Ph.D.  
Senior Manager, Regulatory Submissions  
Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway  
MALVERN PA 19355

Re: K051133  
Trade/Device Name: ARCADIS Avantic  
Regulation Number: 21 CFR 892.1720  
Regulation Name: Mobile x-ray system  
Regulatory Class: II  
Product Code: IZL  
Dated: April 29, 2005  
Received: May 3, 2005

Dear Dr. Andrews:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K051133  
Device Name: ARCADIS Avantic

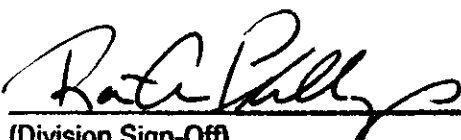
## Indications For Use:

The ARCADIS Avantic is a mobile x-ray system which can operate in six different modes: Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy, Digital Cine Mode (DCM), Subtraction, and Roadmapping, which are necessary to perform a wide variety of clinical procedures. Clinical applications may include, but are not limited to, card/vascular, gastroenterology, electrophysiology, urologic, orthopedic, neurologic, pediatrics, endoscopy, pain therapy and emergency room procedures

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Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-The-Counter Use ☐  
(Per 21 CFR 801.109)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K051133